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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,857	11/07/2000	Kathryn Armour	620-117	5675

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	PAPER NUMBER
1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,857	ARMOUR ET AL.	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-21,23-29,31-33,37-42,46-65 and 68-78* is/are pending in the application.

4a) Of the above claim(s) *31* is/are withdrawn from consideration.

5)☒ Claim(s) *16-21,23-29,32,33,37-40,64,68,69 and 71-78* is/are allowed.

6)☒ Claim(s) *41, 46-63, 65 and 70* is/are rejected.

7)☒ Claim(s) *42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 16-21, 23-29, 31-33, 37-42, 46-65 and 68-78 are pending.

2. Claim 31 stands withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.

3. Claims 16-21, 23-29, 32-33, 37-42, 46-65 and 68-78 are being acted upon in this Office Action.

4. The rejection of claims 16-21, 23-29, 32, 37-41, 46-65, and 68-70 under 35 U.S.C. 112, second paragraph, as being indefinite has been obviated by the claims amendment filed October 28, 2008.

5. The rejection of claims 16-21, 23-29, 32, 37-39, 41, 46-49 and 50-65 under 35 U.S.C. 103(a) as being unpatentable over WO 94/29351 publication (published December 22, 1994; PTO 892) in view of Greenwood et al, Eur J Immunol 23: 1098, 1993; PTO 1449) has been obviated by the claims amendment filed October 28, 2008.

6. The rejection of claims 68-70 under 35 U.S.C. 103(a) as being unpatentable over WO 94/29351 publication (published December 22, 1994; PTO 892) in view of Greenwood et al, Eur J Immunol 23: 1098, 1993; PTO 1449) as applied to claims 16-21, 23-29, 32, 37-39, 41, 46-49 and 50-65 and further in view of Griffin et al (Blood 86: 4430, Dec 1995; PTO 892) has been obviated by the claims amendment filed October 28, 2008.

7. The following new grounds of rejection is necessitated by the amendment filed October 28, 2008.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 41, 46, 49-58 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,015,555 (newly cited filed May 19, 1995; PTO 892).

The '555 patent teaches a binding molecule such as chimeric antibody such as 128.1 that binds to transferring receptor wherein the reference binding molecule comprises a binding domain such as the murine immunoglobulin variable regions of antibody capable of binding a target molecule such as transferrin receptor and an effector molecule such as human constant region having an amino acid sequence that is at least 98.6% identical to the claimed effector domain comprising a chimeric CH2 domain of SEQ ID NO: 2 (see abstract, reference SEQ ID NO: 30 and sequence alignment below, col. 4, line 41, col. 5, lines 39-67, col. 6, lines 1-23, col. 19, lines 30, col. 28, line 15-53, in particular).

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SEQ ID NO: 2          1 APPVAGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSHEDPEVQFNWYVDGVEVHNAKTKP 60
                        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db          1 APPVAGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSHEDPEVQFNWYVDGVEVHNAKTKP 60

          Qy         61 REEQFNSTFRVVSVLTVVHQDWLNGKEYKCKVSNKGLPSSIEKTISKTK 109
                        |||||||||||||||||||||||||||||||||||: |||||||||
          Db         61 REEQFNSTFRVVSVLTVVHQDWLNGKEYKCKVSNKGLPAPIEKTISKTK 109
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Given the prior art effector domain has the same structure as the claimed effector domain, the reference effector domain (Fc) would have had the inherent property of binding to the target molecule, cell mediated destruction of the target, capable of specifically binding to FcγRIIb, reduced affinity for FcγRI, FcγRIIa and FcγRIII and reduced ability to mediate complement lysis. The reference binding domain derives from a different source, i.e., murine as compared to the effector domain, i.e., human constant region (see col. 5, line 30-33, in particular). The '555 patent further teaches a preparation comprising the reference antibody and a pharmaceutical acceptable carrier such as DPBS or sodium phosphate (see col. 9, line 28-30, in particular). The '555 patent also teaches a method of producing the reference chimeric antibody by introducing into a host cell such as SP2/0 cells a vector such as pBSK4600, pAH4625, pAH4807, or pAH4808 linked to a promoter comprising nucleic acid such as DNA comprising the nucleotide

sequence encoding the effector domain of the reference chimeric antibody (see nucleotide sequence in FIG 17J, in particular) or the DNA sequence encoding the reference chimeric antibody (see col. 28, line 15-62, reference SEQ ID NO: 14 and SEQ ID NO: 18, col. 28, lines 15-62, FIGURES 14-16, col. 28, lines 65 through col. 29, line 4, in particular), culturing the host cell under conditions such that the reference chimeric antibody is produced and isolating the reference binding molecule (see col. 28, antibody production by transfectants, in particular). The '555 patent further teaches a method of binding the target molecule such as transferring receptor by contacting the reference antibody with the transferring receptor *in vitro* or *in vivo* under conditions to allow binding (see col. 9, line 10 through col. 14, in particular). Thus, the reference teachings anticipate the claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 41, 47-48, 57, 59-62 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 6,015,555 (newly cited filed May 19, 1995; PTO 892) in view of Griffin et al (of record, Blood 86: 4430, Dec 1995; PTO 892).

The teachings of the '555 patent have been discussed supra.

The invention in claim 47 differs from the teachings of the reference only in that the binding molecule wherein the target molecule is a human platelet antigen (HPA).

The invention in claim 48 differs from the teachings of the reference only in that the binding domain is the binding site of an anti-HPA-1a instead of the binding site of transferrin antibody.

The invention in claim 59 wherein the method of binding the target molecule inhibits the binding of a second binding molecule to the target molecule.

The invention in claim 60 wherein the method of binding the target molecule inhibits the binding of a second antibody to the target molecule.

The invention in claim 61 wherein the method of binding the target molecule wherein the target molecule is HPA-1a.

The invention in claim 62 wherein the method of binding the target molecule inhibits the binding wherein the target molecule is in patient suffering from autoimmune thrombocytopenia.

The invention in claim 70 differs from the teachings of the reference only in that the binding molecule wherein the target molecule is a human platelet antigen HPA-1a.

Griffin et al teach human platelet antigen HPA-1 is the most important platelet alloantigen clinically (see page 4430, col. 1, in particular). Griffin et al teach 98% of the Caucasian population carry HPA-1a (GPIIIa Leu 33), HPA-b1 (GPIIIa pro33) homozygotes are at risk of producing GPIIIa leu 33-specific antibodies after transfusion (post transfusion purpura) or during pregnancy, against paternally inherited GPIIIa leu 33 present on fetal platelets (neonatal alloimmune thrombocytopenia), see page 4430, col. 1, in particular. Griffin et al teach antibodies that bind to human platelet antigen such as HPA-1a (see Table 2, in particular) and such antibodies have both diagnostic and potential therapeutic applications, see abstract, page 4435, col. 1, last paragraph, in particular. The binding of the reference anti-HPA-1a to the target molecule HPA-1a obviously inhibits the binding second molecule such as autoantibody to HPA-1a in patient suffering from autoimmune thrombocytopenia.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the binding domain capable of binding to transferrin receptor in the binding molecule comprising the effector domain comprises chimeric CH2 domain that is at least 98% identical to the claimed SEQ ID NO: 2 of the '555 patent for the binding domain of the antibody that binds specifically to the target antigen HPA-1 as taught by Griffin et al.

One having ordinary skill in the art would have been motivated to substitute because Griffin et al teach such antibodies that bind to such HPA-1a antigen have both diagnostic and potential therapeutic applications, see abstract, page 4435, col. 1, last paragraph, in particular.

14. Claims 48 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 6,015,555 (newly cited filed May 19, 1995; PTO 892) in view of Griffin et al (of record, Blood 86: 4430, Dec 1995; PTO 892) as applied to claims 41, 47-48, 57, 59-62 and 70 mentioned above and further in view of US Pat 5,846,534 (newly cited, Filed April 29, 1995; PTO 892).

The combined teachings of the '555 patent and Griffin et al have been discussed supra.

The invention in claim 48 differs from the teachings of the references only in that the binding domain is anti-CD52 instead of binding domain of anti-transferrin antibody.

The invention in claim 65 differs from the teachings of the references only in that the anti-CD52 binding domain is CAMPATH-1.

The '534 patent teaches binding domain such as heavy and light chain variable domains of Campath-1 (also known as CD52) antibody YTH 34.5 (see entire document, claims 1-6 of the '534 patent, Figure 2, col. 6, line 25-30, in particular). The '534 patent further teaches humanized antibody that binds to CAMPATH-1 is useful for treatment of autoimmune disease, or organ graft rejection (see col. 4, line 23-33, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the binding domain capable of binding to transferrin receptor in the binding molecule comprising the effector domain comprises chimeric CH2 domain that is at least 98% identical to the claimed SEQ ID NO: 2 of the '555 patent for the binding domain of the antibody that binds specifically to the target antigen CAMPATH-1 as taught by the '534 patent.

One having ordinary skill in the art would have been motivated to substitute because the '534 patent teaches humanized antibody that binds to CAMPATH-1 is useful for treatment of autoimmune disease, or organ graft rejection (see col. 4, line 23-33, in particular).

15. Claim 42 stands objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claims 16-21, 23-29, 32-33, 37-40, 64, 68-69 and 71-78 are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9: 00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.

19. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
January 16, 2009